

Interoperability and Patient Access

The rule is requiring holders of Medicare and Medicaid health information (Medicare Advantage, State Medicaid FFS, Medicaid Managed Care, some CHIP, and QHPs in the Federal Marketplace) to make information available to consumers enrolled in their programs. There are two types of information that CMS is proposing to require:

- Information specifically about the individual such as their current and past medical conditions and care received (including adjudicated claims (including cost); encounters with capitated providers; provider remittances; enrollee cost-sharing; and clinical data, including laboratory results (where available)). Note that information availability is generally one-day after information is received or a claim adjudicated.
- Information that is of general interest and should be widely available, such as plan provider networks, the plan's formulary, and coverage policies. CMS is also requiring patient education tools be available (though not necessarily through an API) about how to use their information.

The information required above must be available through open (that is, standards-based) application programming interfaces (APIs) that allow the consumer to access their information through an application without special effort. The base for this open/standards-based API is the Health Level 7 (HL7®) Fast Healthcare Interoperability Resources (FHIR®) standard. Proprietary APIs that may have been acceptable for certification to the 2015 Edition CEHRT program for providers or in use by various payers will not meet the requirements in this regulation for open and available access. Interestingly, throughout the rule, CMS is noting that they are ill-suited to keep up-to-speed on new versions of standards that may be required by regulated entities. Therefore, they are making allowances in situations where a new version of a required standard is adopted. In these cases, the entity adopting the new standard would be deemed compliant with requirements as long as the new standard is backward-compatible with the regulatory-required standard and does not interfere with patient access to information. CMS asks for comment on this piece.

Consumers should be able to gather their information in any application they choose through the invocation of the individual right of access in HIPAA. CMS provides some level of background and cross-referencing to the Office of Civil Rights on the requirements for Covered Entities to release information to consumers. Most of the information contained in the rule relating to the individual right of access is a restatement of previous OCR information. However, there is some language that is intended to address concerns from Covered Entities about release of information to applications that may not meet security requirements that a CE might like to see. In sum, CMS states, again, that once a consumer invokes their individual right of access and directs their information outside of the CE, the CE is "not responsible under the HIPAA Rules for the security of PHI once it has been received by a third-party application chosen by an individual." This is intended to both alleviate concern with

sharing and remind CEs that they may not refuse to release information due to concerns with how a third-party may use the information. CMS also points to the new “Information Blocking” proposed rule promulgated by ONC, including additional technical requirements for complying with the rule.

Section V requires that, moving forward, payers will be required to establish a “Coordination of Care Transaction”. Payer and claim information about a specific patient would be required to be moved when an enrollee moves from one payer to another and then integrated into the new payer’s systems. The goal with this is to avoid duplication of services, redundancy of step-therapies, and general coordination of care for the individual. Plans will be required to respond to the request for information from patients/enrollees for 5 years after the enrollee leaves coverage.

Timing: Subject to the exemptions outlined below, the entities to be regulated will be required to comply with these requirements by January 1, 2020.

Other general themes:

- Health care is far behind other industries in the aggregation and use of information. CMS repeatedly points to banking, online shopping, and other consumer-facing sectors that use APIs and other technologies to advance specific, consumer-centric activity. Much of this commentary is trying to reduce potential push-back that API usage is abnormal and that health care is not (or potentially cannot) get ready to use these.
- CMS flags this rulemaking is a way to promote transparency and value-based care. They argue at several junctures that consumers will appreciate the transparency and make better decisions about their care if they are armed with better information. They also point out that information related to past care, diagnosis, and claims will help consumers better communicate with their providers and, as applicable, new insurance carriers.
- Publication of APIs (FHIR end-points): CMS is requiring that the regulated entities publish their APIs in a publicly available page so that third-party applications can map to them. Fees for accessing this information would mean that the regulated entity does NOT meet the relevant requirements. This requirement is connected back to the ONC NPRM for providers and others subject to the CEHRT requirements in MIPS and the PIP.

Note there are some exceptions to the rules (Some exceptions for parts of the requirements for State CHIP FFS programs and some MA-PDs; no requirements for areas where CMS has no jurisdiction—like employer sponsored plans). Some of these plans are completely exempted while others are not required to comply with a few of the requirements. Regardless of complete exemption or partial, there are encouragements for these entities to participate in these API and data transparency activities but they are generally not required to participate.

CMS also includes an RFI for using APIs for information sharing between providers and payers: While there are a number of ways to exchange information, CMS is requesting feedback on how bulk transfers through APIs for “shared populations” may work.